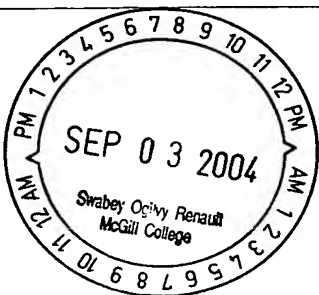


PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To: AD

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Montreal, Quebec H3A 2Y3
CANADA



PCT

REPLY TO:
WRITTEN OPINION

(PCT Rule 66)

DUE ON OCT 31 2004

Date of mailing
(day/month/year)

31.08.2004

Applicant's or agent's file reference
15228-15pct ✓

REPLY DUE

within 2 month(s)
from the above date of mailing

International application No.
PCT/CA 03/01248

International filing date (day/month/year)
25.08.2003

Priority date (day/month/year)
26.08.2002

International Patent Classification (IPC) or both national classification and IPC
A61B19/00

Applicant
ORTHOSOFT INC.

1. This written opinion is the **second** drawn up by this International Preliminary Examining Authority.
2. This opinion contains indications relating to the following items:
 - I ☒ Basis of the opinion
 - II ☐ Priority
 - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - IV ☐ Lack of unity of invention
 - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - VI ☐ Certain documents cited
 - VII ☐ Certain defects in the international application
 - VIII ☐ Certain observations on the international application
3. The applicant is hereby **invited to reply** to this opinion.

When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also: For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.
For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.
4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 26.12.2004

Name and mailing address of the international preliminary examining authority:



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I. Basis of the opinion

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed"*):

Description, Pages

1-14 as originally filed

Claims, Numbers

1-26 as originally filed

Drawings, Sheets

1/6-6/6 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been and will not be examined in respect of:

☐ the entire international application,

☒ claims Nos. 14-24

because:

☒ the said international application, or the said claims Nos. 14-24 relate to the following subject matter which does not require an international preliminary examination (specify):

see separate sheet

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos.

2. A written opinion cannot be drawn due to the failure of the nucleotide and/or amino acid sequence listing to comply with the Standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the Standard.

☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	
Inventive step (IS)	Claims	1-13, 25, 26
Industrial applicability (IA)	Claims	

2. Citations and explanations

see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Claims 14-24 relate to a method for treatment of the human or animal body by surgery, in particular the step: "placing said at least two spinal implants" (claim 14, line 20).

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1-13, 25 and 26 does not involve an inventive step in the sense of Article 33(3) PCT.

1.1 Document DE-A-10057023 (D1) already discloses (see abstract; col. 4, lines 25-55; Fig. 1):

An apparatus for planning a surgery, comprising:

a display 13 for an image representing a patient's anatomy;

a database of virtual bone fragments (see col. 4, lines 45-55);

a tool for a user to manipulate and place said bone fragments in said image at desired locations; and

a positioning module (implicitly present in the computer of D1, since the position of the bone fragments can be rearranged to fit a preferred outline ("sollposition") M1) for calculating a position of a first of said virtual bone fragments with respect to a second of said virtual implants and allow said user to align ("ausrichten") said first and second bone fragments with respect to each other.

1.2 It would be an obvious modification for the skilled person, to make the system of D1 suitable for rearranging and aligning multiple virtual implants in stead of bone fragments. Such systems with databases with virtual implants that can be rearranged on a display are well known in the art, see for instance **US-A-20020038085 (D2)**, page 1, paragraph 0011. Thus he would end up with a system as claimed in claim 1 without using any inventive skill.

**WRITTEN OPINION
SEPARATE SHEET**

International application No. PCT/CA 03/01248

1.3 Therefore, the subject-matter of claim 1 lacks inventive step. The computer program of D1 is also capable of executing the alignment program for implants in stead of bone fragments, therefore independent claims 25 and 26 also lack inventive step.

1.4 Dependent claims 2-13 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of inventive step since these features are either already known from D1 or D2 or they merely are minor modifications of the systems of D1 or D2.